SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Product

Distributor

SOLA Pharmaceuticals
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NDC Number

70512-797-01 / 24 (200mg per 100mL)
70512-798-01 / 24 (400mg per 200mL)

Section 2: Hazard(s) Identification

Section 2, Hazard(s) Identification

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/Information on Ingredients

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Ingredient	CAS Number	EU EINECS/ELINCS List	CHS Classification	%
Hydrochloric Acid	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	***
Sodium Hydroxide	1310-73-2	215-185-5	Skin Corr. 1A (H314)	***
Ropivacaine Hydrochloride	132112-35-7	Nost listed	Acute 4; H302 Aquatic Acute 3; H402 Aquatic Chronic 3; H412	0.2

Ingredient	CAS Number	EU EINECS/ELINCS List	CHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not listed	*
Sodium Chloride	7647-14-5	231-598-3	Not listed	*
Citric Acid, Anhydrous	77-92-9	201-069-1	Not listed	*
Sodium Citrate, Dihydrate	6132-04-3	Not listed	Not listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
* Proprietary
** to adjust pH

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mention in this Section, see Section 16

Section 4: First-Aid Measures

Section 4, First-Aid Measures

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure:

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:

Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning /Collecting:
Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage

Section 7, Handling and Storage

Precautions for Safe Handling
Minimize generating airborne mists and vapors. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions:
Store as directed by product packaging.

Specific end use(s):
Pharmaceutical drug product

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure Controls / Personal Protection

Control Parameters

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit	2ppm
Australia PEAK	5 ppm
	7.5 mg/m^3
Austria OEL - MAKs	5 ppm

	8 mg/m^3
Belgium OEL - TWA	5 ppm
	8 mg/m^3
Bulgaria OEL – TWA	5 ppm
	8 mg/m^3
Cyprus OEL – TWA	5 ppm
	8 mg/m^3
Czech Republic – OEL – TWA	8 mg/m^3
Estonia OEL – TWA	5 ppm
	8 mg/m^3
Germany – TRGS 900 – TWAs	2 ppm
	3 mg/m^3
Greece OEL – TWA	5 ppm
	7 mg/m^3
Hungary OEL – TWA	8 mg/m^3
Ireland – OEL – TWAs	5 ppm
	8 mg/m^3
Italy OEL – TWA	5 ppm
	8 mg/m^3
Japan – OELs – Ceilings	2ppm
	3.0 mg/m^3
Latvia – OEL – TWA	5 ppm
	8 mg/m^3
Lithuania OEL – TWA	5 ppm
	8 mg/m^3
Luxembourg OEL – TWA	5 ppm
	8 mg/m^3
Malta OEL – TWA	5 ppm
	8 mg/m^3
Netherlands OEL – TWA	8 mg/m^3
Poland OEL – TWA	5 mg/m^3
Portugal OEL – TWA	5 ppm
	8 mg/m^3
Romania OEL – TWA	5 ppm
	8 mg/m^3
Slovakia OEL – TWA	5 ppm
	8 mg/m^3
Slovenia OEL – TWA	5 ppm
	8 mg/m^3
Spain OEL – TWA	5 ppm
	7.6 mg/m^3
Switzerland OEL – TWAs	2 ppm
	3.0 mg/m^3
Vietnam OEL – TWAs	5 mg/m^3
SODIUM CHLORIDE	
Latvia OEL – TWA	5 mg/m^3
Lithuania OEL – TWA	5 mg/m^3

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL – MAKs	2 mg/m^3
Bulgaria OEL – TWA	2 mg/m^3
Czech Republic OEL – TWA	1 mg/m^3
Estonia OEL – TWA	2 mg/m^3
France OEL – TWA	2 mg/m^3
Greece OEL – TWA	2 mg/m^3
Hungary OEL – TWA	2 mg/m^3
Japan = OELs – Ceilings	2 mg/m^3
Latvia OEL – TWA	0.5 mg/m^3
OSHA – Final PELS – TWAs	2 mg/m^3
Poland OEL – TWA	0.5 mg/m^3
Slovakia OEL – TWA	2 mg/m^3
Slovenia OEL – TWA	2 mg/m^3
Sweden OEL – TWA	1 mg/m^3
Switzerland OEL – TWA	2 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Ropivacaine hydrochloride

Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Section 9, Physical and Chemical Properties

Physical State	Solution
Color	No data available
Odor	No data available
Odor Threshold	No data available
Molecular Formula	Mixture
Molecular Weight	Mixture
Solvent Solubility	No data available
Water Solubility	Soluble
pH	No data available
Melting/Freezing Point (°C)	No data available
Boiling Point (°C)	No data available

Partition Coefficient: (Method, pH, Endpoint, Value)

Ropivacaine hydrochloride
No data available Log P 2.15

SODIUM CHLORIDE
No data available

HYDROCHLORIC ACID
No data available

SODIUM HYDROXIDE
No data available

Water for Injection
No data available

Sodium citrate, dihydrate
No data available

Citric acid, anhydrous
No data available

Decomposition Temperature (°C)
No data available

Evaporation Rate (Gram/s)
No data available

Vapor Pressure (kPa)
No data available

Vapor Density (g/mL)
No data available

Relative Density
No data available

Viscosity
No data available

Flammability	
Autoignition Temperature (Solid) (°C)	No data available
Flammability (Solids)	No data available
Flash Point (Liquid) (°C)	No data available
Upper Explosive Limits (Liquid) (% by Vol)	No data available
Lower Explosive Limits (Liquid) (% by Vol)	No data available

Section 10: Stability and Reactivity

Section 10, Stability and Reactivity

Reactivity	No data available
Chemical Stability	Stable at normal conditions
Possibility of Hazardous Reactions	
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products	No data available

Section 11: Toxicological Information

Section 11, Toxicological Information

Information On Toxicological Effects

Short Term	Anesthetic drug: may cause central nervous system and cardiovascular system effects
Known Clinical Effects	May cause tingling/itching (paresthesia), allergic reaction, decrease in blood pressure (hypotension), decreased heart rate (bradycardia), respiratory Depression

Acute Toxicity: (Species, Route, End Point, Dose)

Ropivacaine hydrochloride

Rat	IV	LD50	9.9 mg/kg
Rat	Oral	LD50	980 mg/kg
Mouse	Oral	LD50	300 mg/kg

SODIUM CHLORIDE

Rat	Sub-tenon injection (eye)	LC50/1hr	>42 g/m^3
Rat	Oral	LD50	3 g/kg
Mouset	Oral	LD50	4g/kg
Rabbit	Dermal	LD50	>10 g/kg

HYDROCHLORIC ACID

Rat	Oral	LD50	238 – 277 mg/kg

Citric Acid, Anhydrous

Rat	Oral	LD50	3000 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation	Rabbit	Mild
Eye Irritation	Rabbit	Mild

Citric Acid, Anhydrous

Skin Irritation	Rabbit	Mild
Eye Irritation	Rabbit	Severe

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effec(s))

Ropivacaine Hydrochloride

2 Generation Reproductive Toxicity	Rat	No route specified	Dose not specified	Negative

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
In Vivo Micronucleus	Rat	Negative

Carcinogen Status

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC Group 3 (Not Classifiable)

Section 12: Ecological Information

Section 12, Ecological Information

Environmental Overview

Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ropivacaine hydrochloride

Green algae	EC50	72 hours	59 mg/L
Daphnia magna (Water Flea)	EC50	48 hours	34 mg/L
Brachydanio rerio (Zebra Fish)	LC50	96 hours	38 mg/L

Persistence and Degradatibility

No data available

Bio-accumlative Potential

Partition Coefficient: (Method, pH, Endpoint, Value)

Ropivacaine hydrochloride

No data available	Log P	2.15

Mobility in Soil

No data available

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

Section 14, Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Section 15, Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Water for Injection

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
REACH – Annex IV – Exemptions from the Obligations of Register	Present
EU EINECS/ELINCS List	231-791-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0%
CERCLA/SARA Hazardous Substances and Their reportable quantities	5000 lb 2270 kg
CERCLA/SARA – Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA – Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
Standard for the Uniform Scheduling For Drugs and Poisons	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Sodium Chloride

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	231-598-3

Sodium Hydroxide

CERCLA/SARA 313 Emission reporting	Not listed
CERCLA/SARA Hazardous Substances and Their reportable quantities	1000 lb 454 kg
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
Standard for the Uniform Scheduling For Drugs and Poisons	Schedule 5 Schedule 6

EU EINECS/ELINCS List	215-185-5

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	201-069-1

Sodium citrate, dihydrate

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Australia (AICS)	Present
EU EINECS/ELINCS List	Not listed

Ropivacaine hydrochloride

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
EU EINECS/ELINCS List	Not listed

Section 16: Other Information

Section 16, Other Information

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.